2. 510(k) SUMMARY

K 111472

Sponsor Name: TGM Medical, Inc.
5145 Golden Foothill Parkway, Suite 175 & 180
El Dorado Hills, CA 95762

SEP - 6 2011

510(k) Contact: Dennis Crane
Emerson Consultants, Inc
12701 Whitewater Drive, Suite 120
Minnetonka, MN 55343
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Date Prepared: August 29, 2011

Trade Name: HELICON Hip System (HHS)

Common Name: Porous-coated hip prosthesis for cementless use

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358, Class II device, Product Code LPH).

Device Description:
The HELICON Hip System (HHS) is a porous-coated, semi-constrained, hip prosthesis designed for either primary or revision hip arthroplasty. The HHS includes a femoral stem, a CoCr femoral head, non-crosslinked UHMWPE insert, acetabular shell and bone screws.

The HHS stem is a monolithic, titanium alloy, tapered hip stem available with a proximal CPTi plasma porous coating. The stem has a dual wedge geometry and is available in both standard and 7mm lateral offsets in sizes ranging from 7.5mm to 24mm. The stems feature a neck shaft angle of 135° and a 12/14 Morse taper trunnion. HHS stems are compatible with the HHS CoCr femoral head and HHS acetabular insert. The HHS CoCr head is highly polished and available in multiple offsets and diameters (22, 28, and 32mm). The HHS acetabular components include a titanium alloy shell and a mating UHMWPE insert. The shell is a hemispherical design, is available with or without screw holes, and employs a CPTi beaded, porous coating. The UHMWPE insert is available in 20° hooded or non-hooded (neutral) configurations in inner diameters of 22, 28, and 32mm. Titanium alloy bone screws are available for additional fixation.

Indications for Use:
The HELICON™ Hip System is designed for total hip arthroplasty.

The indications for use are:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.

B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C. Proximal femoral fractures.
D. Avascular necrosis of the femoral head.
E. Non-union of proximal femoral neck fractures.
F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities

The HELICON™ hip stem is indicated for cementless use. The HELICON™ acetabular shell component is indicated for cemented or cementless use.

Substantial Equivalence:

Technological Characteristics/Substantial Equivalence:
The HHS is equivalent to predicate systems in design geometry, materials, performance testing and indications for use. Consensus Orthopedics, Inc. (COI) licensed their previously cleared hip components to TGM Medical, Inc. The hip components consist of the previously cleared TaperSet Hip System femoral stem (K102399), CoCr femoral heads (K922561, K960339, and K960156), UHMWPE inserts (K922561 and K020153), acetabular shell (K922561) and titanium bone screws (K922561). The HHS hip components therefore have the same technological characteristics to those used in the Consensus Taper Set Hip System. Based on the identical material, characterization data, geometry and mechanical testing, the HHS system is substantially equivalent to legally marketed predicates (Table 2.1).

Table 2.1: Legally marketed devices to which substantial equivalence is claimed:

510(k) Number	Trade Name	510(k) holder	510(k) Release Date
K922561	Consensus Total Hip System	U.S. Medical Products, Inc.	07/21/1993
K960339	Consensus 22mm CoCrMo Femoral Head	U.S. Medical Products, Inc.	02/21/1996
K960156	Consensus 32mm CoCrMo Femoral Head	U.S. Medical Products, Inc.	02/21/1996
K960340	Consensus Apex Dome Hole Plug	U.S. Medical Products, Inc.	03/15/1996
K102399	Consensus TaperSet Hip System	Consensus Orthopedics, Inc.	12/02/2010
K100933	CS2 Plus Acetabular Insert	Consensus Orthopedics, Inc.	10/06/2010
K020153	Consensus Acetabular Shell, Ti Coated	Hayes Medical, Inc.	04/15/2002

Non-Clinical Performance Data:
COI provided rights to reference their 510(k)s and supporting performance testing. The HELICON Hip System (HHS) implant components use the identical materials, design construct features (e.g., including locking mechanisms of the polyethylene insert to the metal shell and the exterior coatings) of the predicate components. No changes were made to the predicate components that required additional testing. The HHS implant components

were evaluated using a Failure Modes and Effects Analysis (FMEA). No additional non-clinical bench testing was deemed necessary over that used in support of the predicates based on identical design and materials.

Predicate bench testing included distal and proximal stem fatigue testing of the worst-case stem consistent with the "Guidance for Industry and FDA Staff Non-clinical Information for Femoral Stem Prostheses;" Range of Motion analysis; CPTi plasma sprayed and CPTi beaded metallic coating characterization per the "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement;" CPTi plasma spray characterization per the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements;" polyethylene insert retention mechanism testing; and bone screw mechanical strength testing. Additionally, modular connection analyses including fretting and corrosion of the metallic femoral heads for compatibility and pin-on-flat testing of the non-crosslinked UHMWPE/CoCr material combination were also performed. Both the CPTi plasma sprayed coating and the CPTi beaded coating characterizations meet the regulatory definition of porous coating for the hip construct per 21 CFR 888.3358.

All of the observed results for the predicate TaperSet Hip System had been found substantially equivalent prior to devices currently marketed. The subject Helicon Hip System is identical in material and design to that of the TaperSet Hip System. Therefore, the subject device is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TGM Medical, Inc.
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Mr. Dennis Crane
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Minnetonka, Minnesota 55343

SEP - 6 2011

Re: K111472
Trade/Device Name: HELICON Hip System (HSS)
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: August 3, 2011
Received: August 5, 2011

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

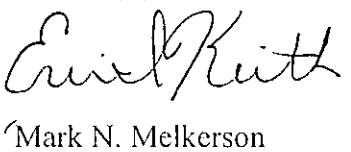
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 111472

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: HELICON Hip System

Indications for Use:

The HELICON™ Hip System is designed for total hip arthroplasty.

The indications for use are:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
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The HELICON™ hip stem is indicated for cementless use. The HELICON™ acetabular shell component is indicated for cemented or cementless use.

Prescription Use ___X___ AND/OR Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mellen

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111472